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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,314	01/22/2004	Michael D. Ries	MLI-10	6544

7590 09/29/2006

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,314	Applicant(s) RIES ET AL.	
	Examiner Bruce E. Snow	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-18, 20 and 40-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-18, 20, 40-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7/27/06 have been fully considered. Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Meulink et al (6,514,288), the amendment to claim 1 overcame this rejection. Regarding claim 40, applicant provides no evidence that the cross sectional shape below the medial tip of the flange is not symmetrical. Referring to figures 8 and 9 of Meulink et al, the cross sections of the stem are symmetric. Additionally, the claim language "substantially radially symmetrical" is very broad. Regarding claim 41, applicant's language does not define over the reference. Again, "substantially" is a broad term. A cylinder large enough to circumscribe the upper portion of the stem would inherently substantially circumscribe the lower portion as well. Regarding claim 42, the new claim language, "... do not differ by more than ten percent.." appears to be new to the entire application. Applicant does not provide evident that the stem of Meulink et al fails to meet this new limitation.

The same reasoning applies to the rejections in view of Burke and Hoffman.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-18, 20, 42, 43-57 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains

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subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

MPEP 714.02 states, "applicant should also specifically point out the support for any amendments made to the disclosure. See **MPEP § 2163.06**." Please in any additional response point out the support for all claim amendments.

Claim 1, "shaped to flex such that, during a normal gait cycle,.." is not found in the original disclosure.

Claim 42, ".. do not differ by more than ten percent.." appears to be new matter.

Claims 43-57 are new matter. Please direct to the specification for support. Unless the specification states the drawings as drawn to scale, applicant cannot use them to support detailed limitations such as ".. do not differ by more than ten percent".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application

by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Meulink et al (6,514,288).

Meulink et al teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

- a femoral head component having an external bearing surface and a female friction fit portion (not shown, inherent);

- a femoral stem component comprising:

 - a neck portion 22 having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

 - a flange portion 24 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

 - a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

 - an elongated stem portion 36 extending distally from the transitional body region

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and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

a distal end tip portion 50 adjacent and distal to the elongated stem portion;

wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Burke (6,179,877).

Burke teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

a femoral head component 12 having an external bearing surface and a female friction fit portion;

a femoral stem component comprising:

a neck portion having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

a flange portion 18 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

an elongated stem portion 14 extending distally from the transitional body region

and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

a distal end tip portion adjacent and distal to the elongated stem portion;

wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

Regarding the boss, see elements 22, 34, 36, 30.

Claims 40-42, 45-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofman et al (EP 0539036).

Hofmann et al teaches a prosthesis adapted for implantation against a resected surface on a proximal end of a femur and inside of an intramedullary cavity of the femur comprising:

a femoral head 20 component having an external bearing surface and a female friction fit portion;

a femoral stem component comprising:

a neck portion 11 having a proximal male friction fit portion, reversibly engagable with the female friction fit portion, and a distal neck body;

a flange portion 12 distal and adjacent to the neck portion, attached to the distal neck body, having an upper portion and a bottom surface;

a transitional body region, adjacent to the bottom surface of the flange portion and extending from the distal neck body;

an elongated stem portion 25 extending distally from the transitional body region and having a longitudinal axis that is orientated at an acute angle from the bottom surface of the flange portion; and

a distal end tip portion adjacent and distal to the elongated stem portion;

wherein the transitional body region has a maximum height of less than thirteen millimeters when measured normal from the bottom surface of the flange to any part of the elongated stem portion.

See flutes 18.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

A handwritten signature in black ink, appearing to be 'Bruce Snow', with a stylized, overlapping loop structure.

BRUCE SNOW
PRIMARY EXAMINER